



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In application of

Docket No: Q90022

Maki IWAHASHI, et al.

Appln. No.: 10/548,089

Group Art Unit: 1615

Confirmation No.: 2099

Examiner: Not yet assigned

Filed: September 06, 2005

For: INDOLE DERIVATIVE COMPOUNDS AND PHARMACEUTICAL AGENTS
COMPRISING THE COMPOUND AS AN ACTIVE INGREDIENT

**SUBMISSION OF ENGLISH TRANSLATION OF
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached please find a copy of an English Translation of the International Preliminary Examination Report received from the Applicants, to advance prosecution in the event such is not readily available from the International Bureau. Claims 1-10, 12 of the application were found to be novel, involve an inventive step and include industrial applicability.

Respectfully submitted,

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: February 17, 2006

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

OHIE, Kunihsa
Ohie Patent Office
Horiguchi No. 2 Bldg. 7F
2-6, Nihonbashi-Ningyocho 2-chome
Chuo-ku, Tokyo 103-0013
JAPON

Date of mailing (day/month/year) 29 September 2005 (29.09.2005)	
Applicant's or agent's file reference ONF-4852PCT	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/001262	International filing date (day/month/year) 06 February 2004 (06.02.2004)
Applicant ONO PHARMACEUTICAL CO., LTD. et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

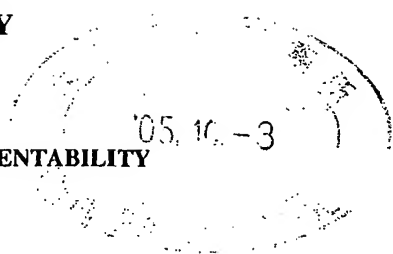
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 70 10

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)



Applicant's or agent's file reference ONF-4852PCT	FOR FURTHER ACTION		Sec item 4 below
International application No. PCT/JP2004/001262	International filing date (<i>day/month/year</i>) 06 February 2004 (06.02.2004)	Priority date (<i>day/month/year</i>) 07 February 2003 (07.02.2003)]	
International Patent Classification (IPC) or national classification and IPC C07C 235/42, 235/46, 237/30, 255/54, 255/58, 323/20, C07D 209/18, 209/30, 213/55, 309/14, A61K 31/192, 31/351, 31/381, 31/404, 31/44, 31/4433, A61P 13/10, 17/02, 29/00, 43/00			
Applicant ONO PHARMACEUTICAL CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 16 September 2005 (16.09.2005) Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div> Telephone No. +41 22 338 70 10
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

Translation

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year) 23-03-2004

Applicant's or agent's file reference

ONF-4852PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/001262

International filing date (day/month/year)

06-02-2004

Priority date (day/month/year)

07-02-2003

International Patent Classification (IPC) or both national classification and IPC

C07C 235/42, 235/46, 237/30, 255/54, 255/58, 323/20, C07D 209/18, 209/30, 213/55, 309/14, A61K 31/192, 31/351, 31/381, 31/404, 31/44, 31/4433, A61P 13/10, 17/02, 29/00, 43/00

Applicant

ONO PHARMACEUTICAL CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Date of completion of this opinion	Authorized officer
Facsimile No.	Telephone No.	

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001262

Box No. I

Basis of the report

1. With regard to the language, this opinion has been established on the basis of:
 - ☐ the international application in the language in which it was filed
 - ☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001262

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims, Nos. 11

because:

☒ the said international application, or said claims Nos. 11
relate to the following subject matter which does not require an international search (*specify*):

Claim 11 pertains to a method for the treatment of the human body by therapy, and thus relates to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

- ☒ no international search report has been established for said claims Nos. 11
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001262

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-10, 12

YES

Claims

NO

Inventive step (IS)

Claims 1-10, 12

YES

Claims

NO

Industrial applicability (IA)

Claims 1-10, 12

YES

Claims

NO

2. Citations and explanations:

The compounds that are set forth in the claims are not disclosed in the documents that are cited in the international search report or in any of the documents that can be considered to be related to the inventions in question which were available to the public prior to the priority date of the present application. Furthermore, the compounds in question are not obvious to a person skilled in the art.

Consequently, claims 1 to 10 and 12 are novel and involve an inventive step.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001262

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/016254 A1 "E, X"	27-02-2003	08-08-2002	09-08-2001

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)